

# EXHIBIT 2

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* MICHAEL I.  
LEVINE, M.D.,

Plaintiff,

v.

VASCULAR ACCESS CENTERS, L.P., and each of its  
subsidiary and/or related corporations, *et al.*,

Defendants.

12 Civ. 5103 (LGS)

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

VASCULAR ACCESS CENTERS, L.P., and each of its  
subsidiary and/or related corporations,

Defendants.

**COMPLAINT-IN-  
INTERVENTION OF THE  
UNITED STATES OF  
AMERICA**

1. The United States of America (the “United States” or “Government”), by its attorney, Geoffrey S. Berman, United States Attorney for the Southern District of New York, having filed a notice of intervention against defendant Vascular Access Centers, L.P., and its

subsidiary and/or related corporations (together, the “VAC Defendants”)<sup>1</sup> pursuant to 31 U.S.C. § 3730(b)(4), alleges for its complaint-in-intervention as follows:

### **PRELIMINARY STATEMENT**

2. This is a civil fraud suit brought by the United States against the VAC Defendants under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (“FCA”), to recover damages sustained by, and penalties owed to the United States as the result of the VAC Defendants’ having submitted false claims to the Government.

3. Vascular Access Centers, L.P., established in 2009, offers vascular medical and surgery services through the VAC Centers, which operated, during the relevant period (i.e., July 9, 2012, through December 31, 2016), in twelve states and Washington, D.C.

4. The VAC Centers provided vascular surgery services to patients with end-stage renal disease (“ESRD”) who received dialysis. Two of the most common procedures performed at the VAC Centers were fistulagrams (a radiological procedure in which dye is injected into the patient’s vein or artery to visualize it) and percutaneous transluminal angioplasties (in which wires and balloons are inserted into veins or arteries that have narrowed in order to restore the blood flow). These patients were all enrolled in Medicare.

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<sup>1</sup> In addition to Vascular Access Centers, L.P., the VAC Defendants include Vascular Access Center of Atlanta LLC; Vascular Access Center of Atlantic County LLC; Vascular Access Center of Bolivar County LLC; Vascular Access Center of Central Jersey LLC; Vascular Access Center of Durham LLC; Vascular Access Center of Eatontown LLC; Vascular Access Center of Georgia LLC; Vascular Access Center of Houston LLC; Vascular Access Center of Jacksonville LLC; Vascular Access Center of Jersey City LLC; Vascular Access Center of Memphis LLC; Vascular Access Center of New Orleans LLC; Vascular Access Center of North Shore Louisiana LLC; Vascular Access Center of Pittsburgh LLC; Vascular Access Center of Prince George County LLC; Vascular Access Center of Seattle LLC; Vascular Access Center of South Atlanta LLC; Vascular Access Center of South Los Angeles LLC; Vascular Access Center of Southern Maryland LLC; Vascular Access Center of Southwest Louisiana LLC; Vascular Access Center of Trenton LLC; Vascular Access Center of Washington DC LLC; and Vascular Access Center of West Orange LLC (collectively, the “VAC Centers”).

5. Pursuant to the Medicare Local Coverage Determinations applicable in the various jurisdictions in which the VAC Centers operated, Medicare would only reimburse a provider for procedures for vascular access evaluation and maintenance, including fistulagrams and angioplasties, on ESRD patients when the patients had certain “diagnostically specific and appropriate indications.”

6. As explained below, the VAC Centers routinely performed fistulagrams and angioplasties on ESRD patients who did not have the requisite “diagnostically specific and appropriate indications.” The VAC Centers then submitted claims to Medicare for those fistulagrams and angioplasties in violation of the FCA. Through this action, the Government seeks to recover damages and penalties under the FCA for those false claims

### **JURISDICTION AND VENUE**

7. This Court has jurisdiction over the claim in this action pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C §§ 1331 and 1345.

8. Venue lies in this District on pursuant to 28 U.S.C. § 1391(b)(2).

### **PARTIES**

9. Plaintiff is the United States of America on behalf of its agency the United States Department of Health and Human Services (“HHS”). The United States filed its notice of partial intervention in this action on July 9, 2018.

10. Relator Michael I. Levine, M.D., is a citizen of the United States and a resident of New York State, who worked for the VAC Defendants from March 2009 to July 2009 as a vascular surgeon. He filed his complaint in this action on June 29, 2012. In addition to his claims against the VAC Defendants, his complaint includes allegations against other defendants who reside in this District regarding events or omissions that took place in this District.

11. Defendant Vascular Access Centers, L.P., established in 2005, is a limited partnership formed under the laws of the Commonwealth of Pennsylvania. Its principal place of business is 2929 Arch Street, Suite 1705, Philadelphia, PA 19104. It is the majority owner of each of the VAC Centers.

12. Vascular Access Center of Atlanta LLC is a limited liability company formed in 2006 under the laws of the State of Georgia. Its principal place of business is 1776 Peachtree Street, N.W., Suite 250, Atlanta, GA 30309.

13. Vascular Access Center of Atlantic County is a limited liability company formed in 2008 under the laws of the State of New Jersey. Its principal place of business is 4622 Black Horse Pike, Suite 102, Mays Landing, NJ 08330.

14. Vascular Access Center of Bolivar County LLC is a limited liability company formed in 2010 under the laws of the State of Mississippi. Its principal place of business is 810 East Sunflower Road, Suite 100B, Cleveland, MS 38732.

15. Vascular Access Center of Central Jersey LLC is a limited liability company formed in 2010 under the laws of the State of New Jersey. Its principal place of business is 1 Wills Way, Central NJ Medical Park, Piscataway, NJ 08854.

16. Vascular Access Center of Durham LLC is a limited liability company formed in 2009 under the laws of the State of North Carolina. Its principal place of business is 3624 Shannon Road, Suite 104, Durham, NC 27707.

17. Vascular Access Center of Eatontown LLC is a limited liability company formed in 2010 under the laws of the State of New Jersey. Its principal place of business is 10 Industrial Way East, Suite 7, Eatontown, NJ 07724.

18. Vascular Access Center of Georgia LLC is a limited liability company formed in 2007 under the laws of the State of Georgia. Its principal place of business is 688 Walnut Street, Suite 201, Macon, GA 31201.

19. Vascular Access Center of Houston LLC is a limited liability company formed in 2007 under the laws of the State of Texas. Its principal place of business is 9230 Kirby Drive, Suite 100, Houston, TX 77054.

20. Vascular Access Center of Jacksonville LLC is a limited liability company formed in 2010 under the laws of the State of Florida. Its principal place of business is 6820 Southpoint Parkway, Suite 1, Jacksonville, FL 32216.

21. Vascular Access Center of Jersey City LLC is a limited liability company formed in 2009 under the laws of the State of New Jersey. Its principal place of business is One Journal Square Plaza, Suite 100, Jersey City, NJ 07306.

22. Vascular Access Center of Memphis LLC is a limited liability company formed in 2007 under the laws of the State of Tennessee. Its principal place of business is 1750 Madison Avenue, Suite 300, Memphis, TN 38104.

23. Vascular Access Center of New Orleans LLC is a limited liability company formed in 2007 under the laws of the State of Louisiana. Its principal place of business is 1 Galleria Boulevard, Suite 110, Metairie, LA 70001.

24. Vascular Access Center of North Shore Louisiana LLC is a limited liability company formed in 2010 under the laws of the State of Louisiana. Its principal place of business is 915 South Harrison Street, Covington, LA 70433.

25. Vascular Access Center of Pittsburgh LLC is a limited liability company formed in 2006 under the laws of the Commonwealth of Pennsylvania. Its principal place of business is 51 Dutilh Road, Suite 100, Cranberry Township, PA 16066.

26. Vascular Access Center of Prince George's County LLC is a limited liability company formed in 2005 under the laws of the State of Maryland. Its principal place of business is 1019 Brightseat Road, Landover, MD 20785.

27. Vascular Access Center of Seattle LLC is a limited liability company formed in 2006 under the laws of the State of Washington. Its principal place of business is 14220 Interurban Avenue South, Suite A110, Tukwila, WA 98168.

28. Vascular Access Center of South Atlanta LLC is a limited liability company formed in 2007 under the laws of the State of Georgia. Its principal place of business is 150 Country Club Drive, Suite 101, Stockbridge, GA 30281.

29. Vascular Access Center of South Los Angeles LLC is a limited liability company formed in 2007 under the laws of the State of California. Its principal place of business is 11411 Brookshire Avenue, Suite 301, Downey, CA 90241.

30. Vascular Access Center of Southern Maryland LLC is a limited liability company formed in 2010 under the laws of the State of Maryland. Its principal place of business is 7615 Matapeake Business Drive, Suite 101, Brandywine, MD 20613.

31. Vascular Access Center of Southwest Louisiana LLC is a limited liability company formed in 2008 under the laws of the State of Louisiana. Its principal place of business is 1340 Surrey Street, Suite 101, Lafayette, LA 70501.

32. Vascular Access Center of Trenton LLC is a limited liability company formed in 2005 under the laws of the State of New Jersey. Its principal place of business is 1450 Parkside Avenue, Unit 18, Trenton, NJ 08638.

33. Vascular Access Center of Washington DC LLC is a limited liability company formed in 2005 under the laws of the District of Columbia. Its principal place of business is 1010 Vermont Avenue N.W., Suite 300, Washington, DC 20005.

34. Vascular Access Center of West Orange LLC is a limited liability company formed in 2007 under the laws of the State of New Jersey. Its principal place of business is 347 Mount Pleasant Avenue, Suite 100, West Orange, NJ 07052.

35. The VAC Defendants currently or previously operated vascular surgery practices in the States of California, Florida, Georgia, Louisiana, Maryland, Mississippi, New Jersey, North Carolina, Pennsylvania, Tennessee, Texas, and Washington, and in the District of Columbia.

## **FACTS**

### **I. Applicable Statutory and Regulatory Scheme**

#### **A. The Medicare Program and Local Coverage Determinations**

36. Pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, the federal Medicare Program was established in 1965 to provide health insurance for elderly and disabled persons. In 1972, Congress expanded Medicare to provide insurance coverage for patients with ESRD, regardless of their age. *See* Pub. L. No. 92-603, § 2991, 86 Stat. 1329, 1463 (1972) (codified at 42 U.S.C. § 1395c).



37. As a general matter, Medicare does not offer coverage for “[e]xaminations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury,” with limited specified exceptions. 42 C.F.R. § 411.15(a)(1).

38. For an ESRD beneficiary, renal dialysis services furnished in or under the supervision of an ESRD facility are paid under the Medicare Part B benefit through a bundled rate that comprises routine maintenance dialysis treatment, including drugs, laboratory tests, equipment, and staff time, as well as monitoring of the patient’s vascular access. *See* 42 U.S.C. § 1395rr(b)(14); 42 C.F.R. part 413, subpart H; Medicare Claims Processing Manual 100-04, ch. 8, § 10. Dialysis-related physician’s services for ESRD beneficiaries are separately paid under Part B through a monthly capitation payment to a designated physician (generally a nephrologist) who is responsible for supervising patients with renal failure, by, among other things, assessing the adequacy of dialysis and managing other conditions secondary to ESRD. *See* 42 U.S.C. § 1395rr(b)(3); 42 C.F.R. § 414.314(a); Medicare Claims Processing Manual 100-04, ch. 8, § 140(A). Outpatient procedures necessary to maintain a patient’s vascular access but not directly related to dialysis, including surgical procedures such as fistulagrams and angioplasties performed at clinics such as the VAC Centers, are paid separately under Part B on a fee-for-service basis. *See generally* 42 U.S.C. § 1395rr(a); 42 C.F.R. § 414.314(b); Medicare Claims Processing Manual 100-04, ch. 8, § 140(B).

39. Under the Medicare statute, “[n]otwithstanding any other provision of this subchapter, no payment may be made under [Medicare] part A or part B for any expenses incurred for items or services . . . which are *not reasonable and necessary for the prevention of illness*.” 42 U.S.C. § 1395y(a)(1)(B) (emphasis added).

40. In submitting a Medicare reimbursement form, a healthcare provider implicitly certifies compliance with § 1395y(a)(1)(B).

41. Deciding what is “reasonable and necessary” under § 1395y(a)(1)(B) is delegated in the first instance to HHS, and the agency may decide whether not to reimburse for certain types of treatments by promulgating national coverage determinations. HHS contracts with Medicare Part B carriers to provide coverage for out-of-hospital medical services, and such carriers may create more refined guidelines, called “local coverage determinations.” These determinations set regional coverage rules that govern in the absence of or as an adjunct to a national policy.

42. Various Medicare Part B carriers have prepared local coverage determinations (the “LCDs”) with respect to vascular access services for patients with ESRD in the states in which the VAC Centers operate. For example, Novitas Solutions, Inc. (“Novitas”, issued LCD L32465, *Hemodialysis Vascular Access Evaluation and Maintenance*, was effective in New Jersey for services performed on or after July 9, 2012, until October 1, 2015. It was superseded by Novitas’s LCD L35064, *Vascular Access for Hemodialysis*, which was effective in New Jersey as well as, as relevant here, in Louisiana, Maryland, Pennsylvania, Texas, and the District of Columbia, from October 1, 2015, until December 31, 2016.

43. LCDs from other Medicare carriers relating to vascular access services for ESRD patients were in effect during the relevant period in other states in which the VAC Centers operated. *E.g.*, First Coast Service Options, Inc., LCD L32830, *Dialysis (AV Fistula and Graft) Vascular Access Maintenance*, effective in Florida from October 9, 2012, through September 30, 2015.

44. For a provider to seek reimbursement for performing a fistulagram, angioplasty or related services on an ESRD patient, the LCDs for the regions in which the VAC Centers operated generally required that the patient have previously undergone a clinical examination that produced diagnostically specific and appropriate clinical findings demonstrating a need for therapies to re-establish physiologically appropriate flow in the dialysis fistula, and that such findings be documented in patients' medical records.

45. For instance, LCD L32465 stated that "[t]ypically, the clinical examination provides adequate information to determine whether there is hemodynamically significant dialysis shunt dysfunction." It then listed clinical findings that "are considered diagnostically specific and appropriate indications to initiate therapies to re-establish physiologically appropriate flow in the dialysis fistula." These included "elevated venous pressure in the AV dialysis access," "prolonged bleeding following needle removal," "loss of 'machine-like' bruit, i.e., short sharp bruit," and "abnormal physical findings, specifically pulsatile graft/fistula or loss of thrill."

46. The LCDs further required that, even in the presence of clinical findings demonstrating a need for therapy generally, angioplasties are considered "reasonable and necessary" only "when the documentation supports the presence of residual, hemodynamically significant stenosis, of greater than or equal to 50 percent of the vessel diameter."

47. In the absence of such clinical findings suggesting the need to re-establish appropriate flow in a dialysis fistula, the LCDs provided that Medicare would not reimburse for fistulagrams, angioplasties or related procedures.

48. The LCDs emphasized that Medicare would not pay for services, including fistulagrams and angioplasties, that were only screening in nature.

**B. The False Claims Act**

49. The False Claims Act reflects Congress’s objective to “enhance the Government’s ability to recover losses as a result of fraud against the Government.” S. Rep. No. 99-345, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266. As relevant here, the FCA establishes civil penalties and treble damages liability to the United States for an individual or entity that:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

31 U.S.C. § 3729(a)(1)(A)-(B).

50. “Knowing,” within the meaning of the FCA, is defined to include reckless disregard and deliberate indifference to the truth or falsity of the information. *Id.* § 3729(b)(1).

51. Submitting a reimbursement request to Medicare for medical procedures that do not comply with an LCD constitutes a false claim actionable under section 3729(a)(1)(A) of the False Claims Act. Creating medical records for medical procedures that make it appear that they comply with the LCD and form the basis of a reimbursement request to Medicare constitutes the creation of false record or statement material to a false claim actionable under section 3729(a)(1)(B) of the False Claims Act.

52. Under the Act, the Government is entitled to recover three times the amount of each claim and, for each claim or overpayment, a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation that occurred prior to November 2, 2015, and a civil penalty of not less than \$10,781 and not more than \$21,563 for each violation that occurred from November 3, 2015, until February 2, 2017.

**II. The VAC Defendants Performed Medical Procedures on ESRD Patients that Did Not Comply with the LCDs and Billed Medicare for Those Procedures**

53. From at least July 9, 2012, to at least December 31, 2016, most VAC Center patients were individuals with ESRD who regularly required and received dialysis. These patients required well-functioning vascular access in order to receive dialysis.

54. The VAC Defendants contracted with physicians to perform fistulagrams, angioplasties, and other procedures on ESRD patients at the VAC Centers.

55. The VAC Centers regularly scheduled ESRD patients for follow-up office visits before it was known whether, at the time of those visits, the patients would exhibit clinical symptoms that would suggest the need to re-establish physiologically appropriate flow in their dialysis fistula.

56. For example, patient KB was seen at a VAC Center on May 3, 2013, and the medical notes stated that he had “no complaints” and that the visit was for a “3 month follow up.” The same patient was seen again on August 12, 2013, and the medical notes indicated that “follow up angiography is planned in 3 months, or sooner should any issues arise.”

57. Similarly, patient DD was seen at a VAC Center on May 15, 2013, and medical notes for her visit indicate that the “follow-up visit/appointment – timeframe” is “3 months.” The patient was seen again on August 21, 2013, and the medical notes for this visit indicate that the reason for her visit is “3 MOFO,” meaning three-month follow up, and indicate that the “follow-up visit/appointment – timeframe” is “3 months.”

58. A review of VAC Center patient visits nationwide between July 9, 2012, and December 31, 2016, shows that patients were routinely seen approximately three months after their last visit, reflecting the VAC Centers’ practice of scheduling regular follow-up visits regardless of whether there was a clinical need for the visits.

59. During these follow up visits and otherwise, the VAC Centers regularly performed, and billed Medicare for, fistulagrams, angioplasties, and related procedures on ESRD patients as a prophylactic or screening measure, even though the patients presented without any documented evidence that they exhibited a need for therapies to re-establish physiologically appropriate flow in the dialysis fistula, such as indications of difficulty with dialysis.

60. For example, in patient DD's visits in May and August 2013, the medical notes indicated that her "hemodialysis access site on the right arm by [the] fistula showed no abnormalities. Thrill palpable, bruit heard." Patient DD had no documented symptoms or clinical findings demonstrating a need for therapies to re-establish flow in the dialysis fistula. Nevertheless, VAC Center physicians performed, and billed Medicare for, fistulagrams and angioplasties during both of these visits.

61. Similarly, the VAC Center medical notes for patient KB's visits on October 9, 2012, and May 3, 2013, indicated that he had an "abnormally functioning dialysis fistula." However, neither the VAC Center records nor the records from the dialysis center for the visits around the same time contain documented symptoms or clinical findings demonstrating a need for therapies to re-establish flow in the dialysis fistula. Nevertheless, VAC Center physicians performed, and billed Medicare for, fistulagrams and angioplasties during both of these visits.

62. Patient GM1 was seen at a VAC Center on December 5, 2012, and March 6, 2013, and on both occasions, the medical notes indicate that her "chief complaint" is that she has "no complaints at this time." No other documented symptoms or clinical findings demonstrating a need for therapies to re-establish flow in the dialysis fistula exist in the VAC Center's medical records for these visits. Nevertheless, VAC Center physicians performed, and billed Medicare for, fistulagrams and angioplasties during both of these visits.

63. Patient GM2 was seen at a VAC Center on February 21 and August 29, 2013, and on both occasions, the medical notes from the VAC Center indicate that she had “low flow,” referring to the flow of blood through the dialysis machine, which is a symptom that may satisfy the LCD criteria. GM2’s medical records for these visits do not reflect any other reason for the visits. However, the records from the dialysis center for this patient’s visits for the week leading up to each visit to the VAC Center do not support the “low flow” entry in the VAC Center’s medical notes; they reflect no decreased flow in the dialysis machines, and indeed include flow measurements that were precisely at the level prescribed by her nephrologist. Nevertheless, VAC Center physicians performed, and billed Medicare for, fistulagrams and angioplasties during both of these visits, apparently based on a false “low flow” rationale.

64. Patient JG was seen at a VAC Center on May 28 and August 27, 2013, and on both occasions, the medical notes from the VAC Center indicate that he had a “history” of “working graft in the left arm with increased pulsatility,” referring to the feeling of the fistula site, which is a symptom that may satisfy the LCD criteria. However, during each of these visits, the notes indicate that “hemodialysis access site on the right arm by [the] fistula showed no abnormalities. Thrill palpable, bruit heard.” No other symptoms documented in JG’s medical records for these visits showed any other reason for the visit or any justification for performing a fistulagram or angioplasty. Furthermore, the records from the dialysis center for this patient’s visits for the week leading up to each visit to the VAC Center record no pulsatility or other abnormalities. Nevertheless, VAC Center physicians performed, and billed Medicare for, fistulagrams and angioplasties during both of these visits.

**CLAIMS FOR RELIEF**

**COUNT ONE**

**(Violation of 31 U.S.C. § 3729(a)(1)(A))**

65. The Government incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

66. By submitting claims for reimbursement of services that did not comply with the LCDs, the VAC Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States.

67. Such acts were made or done knowingly, as defined in 31 U.S.C. § 3729(a)(1).

68. By reason of the VAC Defendants' above conduct, they are liable to the United States for treble damages and penalties, in an amount to be determined at trial.

**COUNT TWO**

**(Violation of 31 U.S.C. § 3729(a)(1)(B))**

69. The Government incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

70. By submitting claims for reimbursement of services that did not comply with the LCDs, the VAC Defendants made, used, or caused to be made or used, false records or statements material to false or fraudulent claims submitted to the United States.

71. Such acts were made or done knowingly, as defined in 31 U.S.C. § 3729(a)(1).

72. By reason of the VAC Defendants' above conduct, they are liable to the United States for treble damages and penalties, in an amount to be determined at trial.

**WHEREFORE**, the United States requests that judgment be entered in its favor and against the VAC Defendants as follows:

- (a) treble the United States' damages, in an amount to be determined at trial, plus an \$11,000 penalty for each claim submitted in violation of 31 U.S.C. § 3729(a)(1)(A) for each violation that occurred prior to November 2,



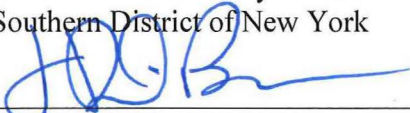
2015, and a \$21,563 penalty for each violation that occurred between November 3, 2015, and February 2, 2017;

- (b) treble the United States' damages, in an amount to be determined at trial, plus an \$11,000 penalty for each claim submitted in violation of 31 U.S.C. § 3729(a)(1)(B) for each violation that occurred prior to November 2, 2015, and a \$21,563 penalty for each violation that occurred between November 3, 2015, and February 2, 2017;
- (d) an award of costs pursuant to 31 U.S.C. § 3729(a)(3); and
- (e) such further relief as is proper.

Dated: October 9, 2018  
New York, New York

GEOFFREY S. BERMAN  
United States Attorney for the  
Southern District of New York

By:



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